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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/358,321	07/21/1999	KITISRI SUKHAPINDA	50.447	1398

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/358,321

Applicant(s)

SUKHAPINDA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-13, drawn to a nucleic acid construct comprising a nucleic acid sequence that encodes an antibody or fragment thereof having the ability to bind to a maize stearyl-ACP Δ -9 desaturase transit peptide, in Paper No. 17, is acknowledged. However, as no grounds for traversal are stated, this election is treated as an election without traverse. Claims 14-23 are cancelled.

The requirement is still deemed proper and is therefore made FINAL. Claims should be amended accordingly to recite only the elected invention.

Priority

A foreign priority is not claimed.

Sequence Listing

Applicant's CRF and paper sequence listing have been entered.

Drawings

There are no drawings in the case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule of SEQ ID NO:31 encoding a single-chain Fv antibody having the amino acid sequence of SEQ ID NO:32, and a method of decreasing the

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steady state level of maize stearyl-ACP Δ -9 desaturase in maize cells using the nucleic acid molecule of SEQ ID NO:31, does not reasonably provide enablement for other antibodies or fragments thereof and methods utilizing other constructs comprising other nucleic acid sequences encoding other antibodies or antibody fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. While one skilled in the art can readily make antibodies to a transit peptide, it is highly unpredictable that all such antibodies would be capable of decreasing the steady state level of the transit peptide's cognate passenger protein. For example, antibodies which are used in diagnostic assays would not necessarily neutralize a target protein's activity.

The claims are drawn to a method of decreasing the steady state level of a passenger protein in a plant cell by transforming a plant cell with a nucleic acid sequence that encodes an antibody or fragment thereof having the ability to bind to a transit peptide. However, in the instant disclosure, Applicants teach only a method of decreasing the steady state level of maize stearyl-ACP Δ -9 desaturase in a maize plant cell by transforming such a cell with a nucleic acid sequence that encodes a single-chain Fv antibody derived from a monoclonal antibody having the ability to bind to the transit peptide of maize stearyl-ACP Δ -9 desaturase (pages 69-70 Example 12). Applicants do not teach any other examples of anti-transit peptide antibodies whose expression results in a decrease in the steady state level of the cognate passenger protein. The specification does not provide any definitive evidence that other anti-transit peptide antibodies will function to decrease the steady state levels of their cognate passenger proteins, such as expressing in a plant cell an anti-transit peptide antibody other than SCAB-TP1. The specification does not provide any definitive guidance for identifying other anti-transit peptide

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antibodies whose expression would result in a decrease in the steady state level of the cognate passenger protein, such as identifying specific structural or physical characteristics of anti-transit peptide antibodies or their cognate passenger proteins that are correlated with decreasing the steady state level of a passenger protein.

Guidance for making and using the claimed invention is necessary for enablement because the ability of an ectopically expressed single-chain Fv antibody to decrease the steady state level of the polypeptide it binds is highly unpredictable. Whitelam et al. teach transgenic tobacco plants comprising a nucleic acid sequence that encodes a single-chain Fv antibody having the ability to bind to phytochrome A (Biochem. Soc. Trans., November 1994, Vol. 22(4):940-944). Although the transgenic plants exhibited altered phytochrome mediated responses, such as light induced seed germination (page 942 Figure 1) and light dependent inhibition of hypocotyl elongation (page 942 Figure 2), the transgenic plants contained apparently wild-type levels of immunochemically detectable phytochrome A polypeptide (page 943 column 1 first full paragraph).

Given the unpredictability of other anti-transit peptide antibodies functioning to decrease the steady state levels of their cognate passenger proteins, the absence of guidance in the specification for making and using such an anti-transit peptide antibody, the lack of any other working examples, and given the breadth of the claims which encompass any method of decreasing the steady state level of any passenger protein in any plant cell by transforming that cell with a nucleic acid sequence encoding any antibody or fragment thereof that binds the passenger protein's transit peptide, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "associated". The nature of the association between the passenger protein and the transit peptide is unclear.

Claim 1 is indefinite in the recitation of "having the ability to bind to a transit peptide". Does the limitation of "having the ability to bind to a transit peptide" apply to "an antibody", to "fragment thereof", or to both?

Claim 1 is indefinite because it is unclear what directs a passenger protein. Is it the transit peptide, the antibody, or the fragment thereof that directs a passenger protein?

Claims 1 and 10 are indefinite in the recitation of "fragment thereof", because it is unclear what types of antibody fragments are encompassed by the claims.

Claim 2 is indefinite in the recitation of the indefinite article "a" in "a nucleic acid construct". Amendment of the claim to recite "the nucleic acid construct" would overcome the rejection.

Claims 3 and 4 are indefinite in the recitation of the indefinite article "a" in "a plant cell". Amendment of the claims to recite "the plant cell" would overcome the rejection.

Claim 3 is indefinite in the recitation of the noun "dicotyledon" to modify the noun "cell". Amendment of claim 3 to recite "The plant cell of claim 2, wherein said plant cell is from a dicotyledonous plant" would overcome the rejection.

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Claim 4 is indefinite in the recitation of the noun "monocotyledon" to modify the noun "cell". Amendment of claim 4 to recite "The plant cell of claim 2, wherein said plant cell is from a monocotyledonous plant" would overcome the rejection.

Claims 5 and 13 are indefinite in the recitation of "derived". What is being retained in the derived product?

Claim 5 is indefinite in the recitation of "derived from the plant cell of claim 2". What is "derived from the plant cell of claim 2", the plant, the progeny thereof, or both?

Claim 6 is indefinite in the recitation of "a maize plant of claim 5", because there is insufficient antecedent basis for "maize" in the claim. Amendment of the claim to recite "The plant of claim 5, wherein said plant is a maize plant" would overcome the rejection.

Claim 7 is indefinite in the recitation of the indefinite article "a" in "a maize plant". Amendment of the claim to recite "the maize plant" would overcome the rejection. Also, the Office interprets "the transit peptide for maize stearyl-ACP Δ -9 desaturase" as there being only one transit peptide for maize stearyl-ACP Δ -9 desaturase.

Claim 10 is indefinite in the recitation of "is a single chain antibody molecule", because it is unclear whether "is a single chain antibody molecule" applies to "said antibody", to "fragment thereof", or to both.

Claim 11 is indefinite in the recitation of "said epitope", because there is insufficient antecedent basis for this limitation in the claim.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 8 is incomplete because it is missing the essential step of antibody expression.

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In the absence of antibody expression, the method of claim 8 does not result in a decrease in the steady state level of a passenger protein.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 16, 2002

Phuong Bui 1/16/02
PHUONG T. BUI
PRIMARY EXAMINER
PHUONG T. BUI
PRIMARY EXAMINER